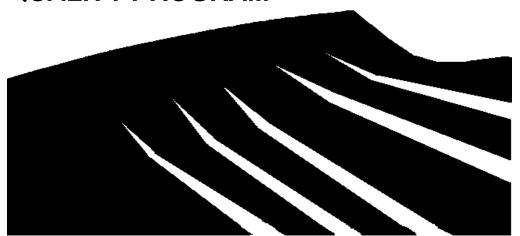
June 2, 1997

LANL-YMP-QP-02.12, R3

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## **EXEMPTION CONTROL**

# LOS ALAMOS QUALITY PROGRAM



APPROVAL FOR RELEASE					
M. J. CLEVENGER - PREPARER Signature on file	DATE Date on file				
M. J. CLEVENGER - QUALITY ASSURANCE PROJECT LEADER Signature on file	DATE Date on file				
G. Y. BUSSOD - LABORATORY LEAD Signature on file	DATE Date on file				

## **Los Alamos**

Yucca Mountain Site Characterization Project

# **HISTORY OF REVISIONS**

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0	01/13/94	N/A	Initial procedure
R1	07/13/94	All	Revised for clarification and to better address QARD requirements
R2	06/03/96	3, 4 & 6	Minor non-substantive editorial changes and to delete the section pertaining to acceptance criteria.
R3	06/02/97	All	To address the new Technical Assurance Project Leader and Office of Quality Assurance representative responsibilities.

## **Los Alamos**

Yucca Mountain Site Characterization Project

### **EXEMPTION CONTROL**

#### 1.0 PURPOSE

This procedure describes the process for taking exemption to Yucca Mountain Site Characterization Project (YMP or Project) Los Alamos National Laboratory (Los Alamos) quality assurance requirements as described in Quality Administrative Procedures (QPs).

#### 2.0 SCOPE

- 2.1 This procedure governs the process for taking exemption to YMP quality assurance requirements as described in Los Alamos QPs.
- 2.2 This procedure applies to Los Alamos and Los Alamos-subcontractor personnel (hereafter referred to as YMP personnel) working under the Los Alamos YMP quality assurance program.
- 2.3 Project Office controlled documents, called grading reports, were issued to define the quality assurance requirements necessary to assure the quality of an activity.

Quality assurance requirements and the implementing documents that satisfy these requirements are now documented in a Requirements Traceability Matrix.

The Project Office identifies and controls Los Alamos YMP work by using the Work Breakdown Structure (WBS). The Project Office assigns WBS numbers at the study plan level. Los Alamos then may assign WBS numbers for specific activities, usually at the eight or greater WBS level. In essence, this procedure describes the process of grading a non-quality affecting activity at the eight or greater WBS level. In some instances, non-quality affecting work within a quality-affecting activity (e.g., prototype or scoping activities) may also be exempted in accordance with QP-03.5. In these cases, this procedure does not apply.

#### 3.0 REFERENCES

LANL-YMP-QP-17.6, Records Management YMP 90-55, Yucca Mountain Site Characterization Project Q-List

#### 4.0 DEFINITIONS

4.1 Exemption Control Process

The Exemption Control process allows Los Alamos YMP personnel to take exemption to quality assurance requirements for selected Los Alamos YMP activities such as prototype, scoping, and non-quality affecting work. Exemptions may be taken for all or part of a quality administrative procedure and are subject to Laboratory Lead approval.

#### 5.0 RESPONSIBILITIES

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

- Laboratory Lead (LL)
- Technical Assurance Project Leader (TAPL)
- Office of Quality Assurance (OQA) representative
- Principal Investigator or higher level management

#### 6.0 PROCEDURE

The use of this procedure must be controlled as follows:

- If this procedure cannot be implemented as written, YMP personnel should notify appropriate supervision. If it is determined that a portion of the work cannot be accomplished as described in this QP, or would result in an undesirable situation, that portion of the work will be stopped and not resumed until this procedure is modified or replaced by a new document that reflects the current work practice.
- Employees may use copies of this procedure printed from the controlled document electronic file; however, employees are responsible for assuring that the correct revision of this procedure is used.
- When this procedure becomes obsolete or superseded, it must be destroyed or marked "superseded" to ensure that this document is not used to perform work.

#### 6.1 Determination of Controls

6.1.1 For selected work activities associated with site characterization data and samples, a **Principal Investigator** or **higher level management** determines if the application of all quality assurance requirements described in Los Alamos implementing documents is appropriate to the work being performed.

The quality assurance program applies to activities related to items on the Yucca Mountain Site Characterization Project Q-list. An activity takes on the same level of importance as the item to which it pertains. Requirements will be applied to the degree commensurate with the following:

- consequence of failure
- importance of any data generated or analyzed
- complexity of implementation of the activity
- reliability of the process
- reproducibility of the results
- necessity for special controls or processes
- degree of standardization
- history of service quality

6.1.2 If the application of requirements is appropriate, no further action is required.

#### OR

- 6.1.3 If requirements are not appropriate, the responsible **Principal Investigator** or **higher level management** may engage the Exemption
  Control process by preparing an Exemption Justification (Attachment 1).
- 6.2 Preparation of an Exemption Justification
  - 6.2.1 The responsible **Principal Investigator** or **higher level management** completes Section I of the Exemption Justification, and submits it to the LL for acceptance.
- 6.3 LL Acceptance
  - 6.3.1 The **LL** reviews the Exemption Justification to determine if it is appropriate to exempt activities from the Los Alamos quality assurance program based on the criteria in subsection 6.1.
  - 6.3.2 If the **LL** accepts the exemption, Section II of the Exemption Justification is completed and the form is submitted to the OQA representative for acceptance.

#### OR

- 6.3.3 If the **LL** does not accept the exemption because the Exemption Justification is incomplete, or further clarification/modification is needed, Section II is filled out, as applicable, and the form is returned to the originator.
  - 6.3.3.1 The **originator** addresses the LL's comments. A new Exemption Justification is used and the former form is discarded. Subsections 6.2 through 6.3 are repeated.
- 6.3.4 If the **LL** disapproves because the request is not justified based on an assessment of the criteria in subsection 6.1.1, Section II is completed, and the Exemption Justification is returned to the requester.

## 6.4 OQA Acceptance

- 6.4.1 The **OQA representative** reviews the Exemption Justification for consistency with programmatic quality assurance requirements.
- 6.4.2 If acceptable, the **OQA representative** completes Section III and forwards the Exemption Justification to the TAPL for processing in accordance with subsection 6.5.

- 6.4.3 If the exemption is not accepted (contrary to programmatic quality assurance requirements), or further clarification/modification is needed, Section III is completed, as applicable, and a copy of the Exemption Justification is returned to the LL and originator.
  - 6.4.3.1 The **originator** initiates a new Exemption Justification or may withdraw the request. If the request is withdrawn, no further action is required.

**NOTE:** If the original request is withdrawn, no records are generated.

### 6.5 Technical Assurance Processing

- 6.5.1 When the TAPL receives an Exemption Justification, the TAPL conducts the following:
  - 6.5.1.1 ensures that both the LL and the OQA representative have accepted the exemption.
  - 6.5.1.2 assigns an identification number. Initial versions are assigned Revision 0.
  - 6.5.1.3 sends the originator a copy; information copies may be sent to appropriate employees (e.g., Technical Assurance Liaisons, Project Leaders, Verification Coordinator, etc.).
  - 6.5.1.4 prepares a record package consisting of the records listed in Section 7.0 and submits it in accordance with QP-17.6.

#### 7.0 RECORDS

The following records generated from this procedure are submitted as a record package.

- Exemption Justification and applicable attachments
- Pertinent information related to this process

#### 8.0 TRAINING REQUIREMENTS

- Prior to conducting work described in Section 6.0, the LL, Technical Assurance Project Leader, OQA representative, and PI require training to this procedure.
- 8.2 Training is accomplished as "read only."

#### 9.0 ATTACHMENTS

Attachment 1: Exemption Justification (1 page)

					TAPL. ONLY LA-EX, R	
	EXEMP <sup>-</sup>	TION JU	JSTIF	ICATION	١	
SECTION I. (Emplo	oyee completes)					
(CHECK ONE)	New	Revision EX,		Deletion of LA- EX, R	_ 🗆	
ORIGINATOR: _	Print Nam	ne .		Signature		
WBS No. and brief	description of exem	ption:				
	DURES FROM WHICATION (Use attac			OVE ACTIVITY BE	EXEMPT.	
SECTION II. (Labo	ratory Lead completes	5)				
(CHECK ONE)	Accepted	Not Accepted		eturned to originato r modifications	r 🔲	
REASON FOR DIS	APPROVAL:					
CONDITIONAL TE	RMS: (if any)					
LL:	Print name		Signature		Date	
SECTION III. (OQA representative completes)						
(CHECK ONE)	Accepted	Not Accepted		eturned to originato r modifications		
REASON FOR DIS	APPROVAL:					
CONDITIONAL TE	RMS: (if any)					
OQA:	Print name		Signature		Date	
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